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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,085	05/03/2006	Shinji Okano	50026/058001	5137

21559 7590 06/22/2009

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
06/22/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/578,085	OKANO ET AL.	
	Examiner	Art Unit	
	QUANG NGUYEN, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-7,10,11 and 13-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-7,10,11 and 13-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/26/08;12/05/08;1/8/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of the CD11c+ dendritic precursor cell as the elected species in the reply filed on 4/9/09 is acknowledged.

In light of the prior art already applied and upon further consideration the species restriction was withdrawn.

Accordingly, amended claims 2-7, 10-11, 13-14 and new claims15-24 submitted in the amendment filed on 12/05/08 are pending in the present application, and they are examined on the merits herein.

Response to Amendment

The rejection under 35 USC 101 because the claimed invention is directed to non-statutory subject matter was withdrawn in light of Applicant's amendment.

The rejection under 35 U.S.C. 102(b) as being anticipated by Steinman et al. (US 6,300,090) was withdrawn in light of Applicant's amendment, particularly with the limitation "Sendai virus vector".

The rejection under 35 U.S.C. 102(b) as being anticipated by Song et al. (US 2002/0123479 A1) was withdrawn in light of Applicant's amendment, particularly with the limitation "Sendai virus vector".

The rejection under 35 U.S.C. 102(b) as being anticipated by Jin et al. (Gene therapy 10:272-277, February 2003; IDS) as evidenced by Romani et al. (J. Exp. Med. 180:83-93, 1994) was withdrawn in light of Applicant's amendment.

The rejections under 35 U.S.C. 103(a) set forth in the Office action mailed on 6/5/08 were withdrawn in favor of the modified 103 rejections below in light of Applicant's amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

New claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. ***This is a new ground of rejection necessitated by Applicant's amendment.***

New claim 20 is dependent on a cancelled claim 1, and therefore the metes and bounds of the claim are not clearly determined as well as it is unclear which prior art would or would not meet all the limitation of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 2-3, 6-7, 11, 13-18 and 23-24 are rejected under 35 U.S.C. 102(a) as being anticipated by Shibata et al. (The 10th Annual Meeting 2004, August 05-06, Poster

088; IDS). ***This is a new ground of rejection necessitated by Applicant's amendment.***

Shibata et al already disclosed immature or non-activated murine dendritic cells were transduced with recombinant Sendai virus vectors (SeV-GFP or SeV-INFbeta) to transducer foreign gene expression and to fully activate them. Shibata et al further taught that turmor-burden mice were treated by intratumoral injection of these activated dendritic cells which where also pulsed with tumor lysate.

Accordingly, the teachings of Shibata et al meet all the limitation of the instant claims. Therefore, the reference anticipates the instant claims.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended claims 2-7, 10-11, 13-14 and new claims 15-19, and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Song et al. (US 2002/0123479 A1) in view of Tokusumi et al. (US 6,746,860; IDS), Jin et al. (Gene therapy 10:272-277, February 2003; IDS), Hwu et al (US 6,734,014) and Waller et al (US 2005/0013810). ***This is a modified rejection necessitated by Applicant's amendment.***

Song et al disclose compositions and methods useful for stimulating an immune response against one or more disease associated antigens, including cancer associated antigens, by genetically modifying dendritic cells including dendritic progenitor cells, *in vivo* or *ex vivo*, wherein the dendritic cells were genetically modified by a recombinant negative strand RNA virus (e.g., vesicular stomatitis virus, paramyxoviruses, orthomyxoviruse and bunyaviruses) directing the expression of at least one disease associated antigen (see at least Summary of the Invention; particularly paragraphs 6-7, 10-12, 16-18, 41 and 60). Song et al also disclose that it has been discovered that the efficiency of immune system stimulation mediated by genetically modifying dendritic cells can be several orders of magnitude greater than that mediated by genetically modified fibroblasts, muscle, and other cell types (paragraph 39). Song et al further disclose that an expression vector may in addition to directing expression of at least one

disease associated antigen, directs the expression of an immunomodulatory factor such as IL-12, IL15, IL-2, beta-interferon among many others (paragraphs 68, 89-90). Song et al also teach that the genetically modifying dendritic cells are typically administered via parenteral or other traditional direct routes or directly into a specific tissue such as into the tumor in the case of cancer therapy in a mammal in need thereof (paragraphs 16-18 and 140).

Song et al did not teach explicitly the use of a Sendai virus vector for genetically modifying immature dendritic cells such as dendritic progenitor cells, even though they disclosed that dendritic cells, including dendritic progenitor cells could be genetically modified by any recombinant negative strand RNA virus including any paramyxovirus; nor did Song et al teach the use of CD34+ or CD11c+ dendritic precursor cells or the step of further culturing the precursor cells with GM-CSF and IL-4.

However, at the effective filing date of the present application, Tokusumi et al already disclosed the preparation of at least a recombinant Sendai virus vector to be used for transfer of foreign genes (see at least the abstract as well as Summary of the Invention). Tokusumi et al further disclosed that the Sendai virus vector is useful for gene therapy due to its safety, high gene transfer efficiency and capacity to express a foreign gene in a high level.

Additionally, Jin et al already disclosed successfully a method in which recombinant Sendai virus was in contact and provided **a highly efficient gene transfer into human cord blood CD34+ cells**, including human cord blood HSCs and more

immature cord blood progenitor cells (see at least the abstract; page 276, col. 1, last paragraph).

Moreover, Hwu et al also taught at least a method of preparing recombinant dendritic cells by transforming a hematopoietic stem cell, including CD34+ cells derived from a variety of sources such as cord blood, bone marrow and mobilized peripheral blood, with a nucleic acid followed by differentiation of the stem cell into dendritic cells in the presence of GM-CSF, TNF-alpha and optionally together with IL-4 (see at least the abstract; col. 9, lines 29-57; col. 10, line 60 continues to line 13 of col. 11; col. 15, lines 15-46).

Furthermore, Waller et al also taught that progenitors of dendritic cells can be identified in many tissues, such as bone marrow and blood, based on the expression of certain cell surface markers; and that dendritic cell progenitors are typically identified by the expression of one or more of the following markers on its cell surface **CD11c**, CD13, CD14, CD33, **CD34** or CD4 (see at least paragraphs 24-28 and 36).

Accordingly, it would have been obvious and within the scope of skill for an ordinary skilled artisan to modify the teachings of Song et al. by also utilizing a recombinant Sendai virus vector for genetically modifying immature dendritic cells, such as CD11c+ and/or CD34+ dendritic precursor cells derived from bone marrow or cord blood to produce mature dendritic cells expressing at least a recombinant disease associated antigen in light of the teachings of Tokusumi et al., Jin et al, Hwu et al and Waller et al as discussed above.

An ordinary skilled artisan would have been motivated to carry out the above modifications because Tokusumi et al already taught that the recombinant Sendai virus vector is useful for gene therapy due to its safety, high gene transfer efficiency and capacity to express a foreign gene in a high level. Additionally, a highly efficient gene transfer in human cord blood CD34+ cells which are dendritic precursor cells has been successfully achieved and demonstrated by Jin et al. Furthermore, dendritic cell progenitors typically identified at least by the expression of one or more of the following markers on its cell surface such as **CD11c** or **CD34**, derived from a variety of sources such as cord blood, bone marrow and mobilized peripheral blood, have been genetically modified for the preparation of mature dendritic cells expressing desired heterologous proteins/peptides as taught by Hwu et al and Waller et al.

The methods and compositions resulted from the combined teachings of Song et al., Tokusumi et al., Jin et al., Hwu et al and Waller et al are indistinguishable from the methods and compositions as claimed by the present application.

An ordinary skilled artisan would have a reasonable expectation of success in light of the teachings of Song et al., Tokusumi et al., Jin et al., Hwu et al and Waller et al., coupled with a high level of skill for an ordinary skilled artisan in the relevant art.

Accordingly, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Response to Arguments

Applicants' arguments related in part to the above modified rejection in the Amendment filed on 12/05/08 (pages 7-14) have been fully considered but they are respectfully not found persuasive.

1. Applicants argue that there was no reasonable expectation that Sendai virus could successfully be used to produce a mature dendritic cell using an immature dendritic cell or a precursor thereof. This is because the primary Song et al reference demonstrated only transduction of dendritic cells with a retrovirus vector and the transduction efficiency of dendritic cells was extremely low. Applicants further cited the teachings of Cremer et al (Hum. Gene Ther. 11:169—1703, 2000; IDS) showing that one could probably obtain IFN-beta-transformed DCs only by transducing CD34+ stem cells (progenitors of dendritic cells) with a recombinant retroviral vector. Applicants further argued that transducing dendritic cells using viral vectors is not trivial and Applicants demonstrated that immature dendritic cells are very efficiently infected with Sendai virus vector, with the gene transfer efficiency to CD34+ precursor cells at 65 to 70% versus the result reported by Cremer et al (<25 or 30%). Applicants further noted that infectivity of Sendai virus to matured dendritic cells was significantly reduced and a highly efficient gene transduction specific to immature dendritic cells using Sendai virus vector was an unpredictable finding of the present invention.

Firstly, the above rejection is made under 35 U.S.C. 103(a) and therefore there is no requirement that the primary Song et al reference has to teach the use of a Sendai virus vector, let alone demonstrating specifically transfection of a precursor of a dendritic cell (e.g., CD34 cells) with a Sendai virus vector. Nevertheless, Song et al

taught specifically compositions and methods useful for stimulating an immune response against one or more disease associated antigens, including cancer associated antigens, by genetically modifying dendritic cells including dendritic progenitor cells, *in vivo* or *ex vivo*, wherein the dendritic cells were genetically modified by a recombinant negative strand RNA virus (e.g., vesicular stomatitis virus, paramyxoviruses, orthomyxoviruse and bunyaviruses) directing the expression of at least one disease associated antigen.

Secondly, the reference to the Cremer et al article in the IDS is irrelevant. Cremer et al did not teach or suggest the use of a Sendai virus for genetically engineering any cell, including CD34+ stem cells.

Thirdly, in contrast to Applicant's position that highly efficient gene transduction to immature dendritic cells or dendritic precursor cells such as CD34 stem cells by Sendai virus vector was unpredictable at the effective filing date of the present application, **the teachings of Jin et al cited in the above rejection indicated otherwise**. It is further noted that the Jin et al reference was applied as a 102(b) reference to previously unamended claim 2 in the Office action dated 6/5/08. Furthermore, Li et al (J. Virol. 74:6564-6569, 2000; IDS) also demonstrated that **a Sendai virus vector mediated a gene transfer and expression in various types of animal and human cells, including non-dividing cells, with high efficiency** (see at least the abstract).

Fourthly, the instant claims do not require any particular transfection efficiency.

2. Applicants further argue that the art of record provides no basis for a reasonable expectation of success with respect to tranducing an immature dendritic cell or a precursor thereof which, in turn, produces mature dendritic cells. This is because the inventors have demonstrated that Sendai virus transduction into immature dendritic cells induces spontaneous maturation of transduced dendritic cells without any stimulation using LPS. The matured dendritic cells are automatically obtained without additional steps unlike retroviral gene transduction into dendritic cells taught by Cremer et al.

Firstly, please refer to the combined teachings of combined teachings of Song et al., Tokusumi et al., Jin et al., Hwu et al and Waller et al, particularly Jin et al already disclosed successfully at least a method in which recombinant Sendai virus was in contact and provided **a highly efficient gene transfer into human cord blood CD34+ cells**, including human cord blood HSCs and more immature cord blood progenitor cells.

Secondly, please note that the methods and compositions resulted from the combined teachings of Song et al., Tokusumi et al., Jin et al., Hwu et al and Waller et al are indistinguishable from the methods and compositions as claimed by the present application.

Thirdly, please also note the open language of the term "comprises" in the method claims, indicating that at least the claimed methods encompass any stimulation steps if desired.

Fourthly, once again the reference to the Cremer et al is irrelevant because it was not used in any rejection in this Office action or in the previous Office action dated 6/5/08. Moreover, the Cremer et al reference teaches exclusively the use of a retroviral vector without any suggestion on the use of a recombinant negative strand RNA virus (e.g., vesicular stomatitis virus, paramyxoviruses, orthomyxoviruse and bunyaviruses), let alone a Sendai virus vector.

3. Applicants further argued that they demonstrated for the first time that immature dendritic cells are readily transduced with Sendai virus vector in comparison with the result of Cremer et al, and such data describes an unexpected property or result from the use of a Sendai virus vector as compared to another viral vector. Such objective evidence are persuasive to overcome any prima facie case of obviousness.

Please refer to the Examiner's responses in the preceding paragraphs, particularly the teachings of Jin et al which demonstrated successfully that recombinant Sendai virus provides a highly efficient gene transfer into human cord blood-derived hematopoietic stem cells which are dendritic precursor cells. Additionally, Li et al (J. Virol. 74:6564-6569, 2000; IDS) already demonstrated that **a Sendai virus vector mediated a gene transfer and expression in various types of animal and human cells, including non-dividing cells, with high efficiency.**

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Amended claims 11, 13-19 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-6 and 8-14 of copending Application No. 11/630,532. ***This is a modified rejection necessitated by Applicant's amendment.***

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The instant claims are directed to an isolated vector-containing mature dendritic cell containing a Sendai virus vector and a method for suppressing tumor growth comprising the step of delivering the same dendritic cell to a tumor cell.

Claims 1, 3-6 and 8-14 of copending Application No. 11/630,532 are drawn to an anticancer agent comprising a dendritic cell introduced with an RNA virus able to

replicate its genome, including the RNA virus encodes an IFN-beta; and a method for suppressing a cancer comprising the step of administering a dendritic cell introduced with an RNA virus able to replicate its genome.

The claims of the present application differ from the claims of the copending Application No. 11/630,532 in reciting specifically Sendai virus vector and mature dendritic cells.

The claims of the present application can not be considered to be patentably distinct over claims 1, 3-6 and 8-14 of copending Application No. 11/630,532 when there are specific disclosed embodiments of the copending Application that teach that the preferred RNA viruses of the invention include paramyxoviridae virus such as Sendai virus (page 5, lines 1-36; and examples); and dendritic cells include both mature and immature dendritic cells (page 8, lines 3-4). Accordingly, the claims of copending Application No. 11/630,532 fall within the scope of claims 11, 13-19 and 24 of the present application.

This is because it would have been obvious to an ordinary skilled artisan to modify the claims of the copending Application by introducing a minus-strand RNA viral vector such as Sendai viral vector into dendritic cells (both mature and/or immature dendritic cells) for the preparation of an anticancer agent, that support the instant claims. An ordinary skilled artisan would have been motivated to do this because these embodiments are explicitly disclosed or taught in the copending Application No. 11/630,532 as preferred embodiments.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In the amendment dated 12/05/08 (page 14), Applicants indicated that Applicants will address the above nonstatutory obviousness double patenting upon an indication of allowable subject matter.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Nelson et al (US 6,479,286) teach methods of differentiating monocytes obtained from a variety sources, such as leukaphresis of peripheral blood mononuclear cells, into dendritic cells, including monocytes that are genetically modified by various recombinant expression vectors (e.g., retrovirus, adenovirus, poxvirus) (see at least Summary of the Invention and col. 15-16).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/QUANG NGUYEN/
Primary Examiner, Art Unit 1633